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Patent and Trademark Office

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/868,200 09/10/01 FUHR

G A34368PCTUSA

021003
BAKER & BOTTS
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NEW YORK NY 10112

HM22/1109

EXAMINER

OZGA, B

ART UNIT

PAPER NUMBER

1651

DATE MAILED:

11/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/868,200

Applicant(s)

FUHR ET AL.

Examiner

Brett T Ozga

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 27-51 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 and 27-51 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 27, 32, 42 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Ronfard et al. (FR 2743421).

The instant application claims a device for cell trace based testing of biological cells with a substrate having surface regions, on which the cells adhere more poorly than on surface track regions, in which the cells adhere well and can move adhesively, wherein the surface track regions are arranged for the adhesion of cell traces consisting of material residues separated from the cells.

Ronfard et al. teach a device for cell trace based testing of biological cells with a substrate having surface regions, on which the cells adhere more poorly than on surface track regions, in which the cells adhere well and can move adhesively, wherein the surface track regions are arranged for the adhesion of cell traces consisting of

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material residues separated from the cells. (See p. 4, line 35 – p. 5, line 20 and page 7 of the description)

It also claims the process of testing of the properties of cells for medical, biochemical and/or pharmacological purposes, or for biocompatible modification of the surfaces of implant materials, by using material residues, which are formed by biological cells as cell traces on substrates.

Since the claim relates very generally to the use of material residues (not necessarily to material residues in the form of traces on substrates), it can be interpreted as referring to the use of surface proteins for this purpose, which is well known in the art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 27-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zeiter (US 4359527) in view of Loken et al. (EP 0347210) and further in view of Ronfard et al.

Claims 1, 27, 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zeiter (US 4359527) in view of Loken et al. (EP 0347210).

The instant application claims a process of detecting the composition of cell traces by staining or marking for the performance of micoranalytic processes. Dependent claims further limit by having the microanalytic processes comprise fluorescence measurements, measurements on the basis of isotope markings or elemental analysis.

Zeiter teaches a diagnostic assay wherein a substratum which is coated with visible particles susceptible to ingestion by capillary endothelial cells. Onto that substratum are plated capillary endothelial cells which, after being allowed to adhere to the substratum, are incubated with the test sample. Following incubations, the area of the phagokinetic track left by at least one of the cells is measured and compared to the area of the track left by a control cell incubated under the same conditions, but in medium lacking test sample. A larger track area left by test cell indicates the presence in the test sample of a factor.

Zeiter does not teach a method for the simultaneous, multi-parameter analysis of cells in a body fluid, wherein the fluid comprises either spinal, peritoneal or brain fluid, urine or whole blood and additionally may comprise a tissue cell suspension, wherein the tissue comprises bone marrow aspirates, lymph node, spleen or liver cells such as

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from a biopsy, and wherein the parameters comprise at least two measures of the light scattering ability of each cell examined and at least three measures of fluorescence emission or activity from each cell examined.

Loken et al. teach a method for the simultaneous, multi-parameter analysis of cells in a body fluid, wherein the fluid comprises either spinal, peritoneal or brain fluid, urine or whole blood and additionally may comprise a tissue cell suspension, wherein the tissue comprises bone marrow aspirates, lymph node, spleen or liver cells such as from a biopsy, and wherein the parameters comprise at least two measures of the light scattering ability of each cell examined and at least three measures of fluorescence emission or activity from each cell examined.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to add the measures of Loken et al. to the assay of Zeiter. The artisan of ordinary skill would have been motivated to have combined the two references for the purpose of achieving a more thorough assay for detecting the composition of cell traces. Thus, in view of the cited references, the artisan of ordinary skill would have been motivated to have practiced the process as recited in the claims.

Claims 1 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zeiter (US 4359527).

The instant application claims a process wherein the cell traces are produced in predetermined surface track regions, which are at least partially microstructured and/or modified for amplified adhesion of the cells.

Zeiter teaches a diagnostic assay wherein a substratum which is coated with visible particles susceptible to ingestion by capillary endothelial cells. Onto that substratum are plated capillary endothelial cells which, after being allowed to adhere to the substratum, are incubated with the test sample. Following incubations, the area of the phagokinetic track left by at least one of the cells is measured and compared to the area of the track left by a control cell incubated under the same conditions, but in medium lacking test sample. A larger track area left by test cell indicates the presence in the test sample of a factor.

Zeiter does not teach predetermined surface track regions, which are at least partially microstructured and/or modified for amplified adhesion of the cells.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to add predetermined surface track regions, which are at least partially microstructured and/or modified for amplified adhesion of the cells to the invention of Zeiter. The artisan of ordinary skill would have been motivated to have modified the teachings of Zeiter in order to achieve better adhesion. Thus, in view of the cited reference, the artisan of ordinary skill would have been motivated to have practiced the process as recited in the claims.

Claims 1,27,32, 42-47 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ronfard et al. in view of the present application.

The instant application claims a device for cell trace based testing of biological cells with a substrate having surface regions, on which the cells adhere more poorly than on surface track regions, in which the cells adhere well and can move adhesively, wherein the surface track regions are arranged for the adhesion of cell traces consisting of material residues separated from the cells.

Ronfard et al. teach a device for cell trace based testing of biological cells with a substrate having surface regions, on which the cells adhere more poorly than on surface track regions, in which the cells adhere well and can move adhesively, wherein the surface track regions are arranged for the adhesion of cell traces consisting of material residues separated from the cells. (See p. 4, line 35 – p. 5, line 20 and page 7 of the description)

Ronfard et al. do not teach the cell treatment and testing techniques of claims 43-47.

However, as indicated on page 3, second paragraph of the application, the cell treatment and testing techniques in claims 43-47 are known in the relevant technical field. Therefore, it would have been obvious to a person of ordinary skill in the art at the

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time the invention was made to apply the method or design options indicated in the application as known in the art to the device of Ronfard et al. in order to solve the problem at hand. Thus, in view of the cited references, the artisan of ordinary skill would have been motivated to have made the device as recited in the claims.

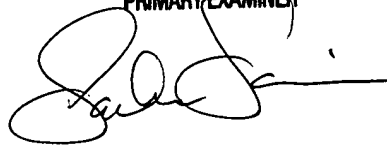
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brett T Ozga whose telephone number is 7033050634. The examiner can normally be reached on M-F 0530-1500, 2nd Wednesday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 7033084743. The fax phone numbers for the organization where this application or proceeding is assigned are 7033084242 for regular communications and 7033053014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 7033080196.

BTO
November 7, 2001

SANDRA E. SAUCIER
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Saucier', with a long horizontal line extending to the right.